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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/722,574 | 11/28/2003 | Allan Tanghoj | P66852US3 | 4958 |
| 136 | 7590 | 08/15/2006 | EXAMINER | |
| JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004 | | | GILBERT, ANDREW M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/722,574 | Applicant(s) TANGHOJ ET AL. | |
| | Examiner Andrew M. Gilbert | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/23/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/11/04, 8/30/04, 3/8/05, 12/8/05, 4/25/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species IV: Figs 12, 13 in the reply filed on 6/23/06 is acknowledged.
2. Claims 2-5, 7-11 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/23/2006.

Acknowledgements

3. The preliminary amendments including the replacement drawing sheets filed have not submitted any new matter and are proper.
4. In the response to the election/restriction requirement submitted 6/23/06 the applicant added new claims 13-20.
5. Thus, claims 1, 6, 12-20 are pending, with claims 1 and 19 being independent.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/184081, filed on 6/28/2002.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on 4/25/2006, 12/8/2005, 3/8/2005, 8/30/2004, and 3/11/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

8. The drawings are objected to because fig 12 has reference number "2", whereas the examiner believes the Applicant intended to reference "82". Additionally, Fig 12 has reference number "88", whereas the specification lack reference number "88" and refers to the ribbed portion by reference number "8". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 6, 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al (WO 00/30575). In reference to claims 1 and 19, Pedersen et al discloses a kit for preparing a catheter for draining a human bladder, the kit comprising at least two catheter sections (1, 3, Fig 1) defining a longitudinally extending passage therein, the sections being fixedly connected by a joint (1, 3, Fig 5; pg 6, lns 33-35) and arranged in a coextending fashion with a tubular protective member (4, Fig 1) surrounding a first, proximal one of said catheter sections, said joint defining a substantially liquid tight seal (Fig 1, 9; pg 7, lns 24-29, pg 8, lns 1-4) at a distal end of a substantially annular and longitudinally extending cavity provided between the proximal end portion of the first catheter section and an inner wall of the tubular protective member (Fig 1, 9; pg 7, lns 24-29, pg 8, lns 1-4), the tubular protective member being removably connected to the second catheter section (Fig 1, 9; pg 7, lns 24-29, pg 8, lns 1-4), so that, when the tubular protective member is removed, a proximal end portion of the first catheter section is exposed and ready for insertion into the human urethra (Fig 1, 5).

11. In reference to claim 6, Pedersen et al additionally discloses wherein a distal end of the second catheter section is provided with a removable liquid-tight seal (Fig 1, 9; pg 7, lns 24-29, pg 8, lns 1-4).

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12. In reference to claim 12 and 20, Pedersen et al additionally discloses wherein the catheter has a hydrophilic surface and a liquid swelling medium is provided in the annular cavity (pg 8, Ins 18-33).

13. In reference to claim 13, Pedersen et al additionally discloses wherein the tubular protective member is detachably attached to an outer surface of the catheter when the tubular protective member is covering the first catheter section (Fig 1, 9; pg 7, Ins 24-29, pg 8, Ins 1-4).

14. In reference to claim 14, Pedersen et al additionally discloses wherein said tubular member includes an outward flange at a distal end thereof (6, 7).

15. In reference to claim 15, Pedersen et al additionally discloses wherein said second catheter section includes an outlet opening in a proximal end thereof that is covered by a foil (11).

16. In reference to claim 16, Pedersen et al additionally discloses further comprising a ribbed portion (1, 3, Fig 5) between said first and second sections.

17. In reference to claim 17, Pedersen et al additionally discloses wherein said tubular protective member fastens to said second catheter section through engagement with said ribbed portion (1, 3, Fig 1; Fig 1, 9; pg 7, Ins 24-29, pg 8, Ins 1-4; wherein the engagement with the ribbed portion occurs through coupling of (10) to (3) and then (9) to (10) shown in Fig 9-10).

18. In reference to claim 18, Pedersen et al additionally discloses wherein the tubular protective member fastens to said second catheter section when the tubular protective member is covering the first catheter section (Fig 1).

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1, 6, 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26, 54-65 of copending Application No. 10/184081 or claims 1-21 of copending Application No. 10/537014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

